(c) whether the Drug Controller General of India sought certain clarifications and expressed reservations for granting permission for clinical trials to another agency which applied for clinical trial of same drug;

(d) if so, whether above clarifications were resolved before granting permission for doing clinical trials; and

(e) whether Government are aware that South Africa denied clinical trials of the above drug?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAM DOSS): (a) to (e) The permission was granted to a Clinical Reserach Organisation (CRO) to conduct a Phase III clinical Trial on Neseritide (Natrecor), manufactured by Johnson and Johnson, USA. Neseritide is already marketed in USA since 2001. It is also marketed in Israel, Switzerland and Argentina.

The permission to conduct the trial was granted after seeking necessary clarifications and submission of reports by the firm. The firm submitted the report where a panel of Expert Cardiologists in USA had recommended the trial. No other company was refused permission to conduct clinical trials with the drug. The sponsors had themselves changed the CRO and notified this Ministry. The firm had submitted copies of approvals of the trial from Canada, Latin America and USA. According to the information provided by the firm recently, the trial has been approved by Medicine Control Council, South Africa and recruitment of patients is ongoing in South Africa.

Envtronmental clearance to Dholera Port

*426. SHRI SURYAKANTBHAI ACHARYA:
SHRI KANJIBHAI PATEL:

Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether it is a fact that a proposal for environmental clearance in respect of Dholera Port has been received by the Central Government from the State Government of Gujarat;

(b) if so, the date on which it was received;

(c) whether the clearance is still pending;

(d) if so, the reasons for such a long period of pendency; and

(e) the time likely to be taken by Government for according approval?

THE MINISTER OF ENVIRONMENT AND FORESTS (SHRI A. RAJA): (a) Yes, Sir.

(b) The Central Government had received the proposal seeking environmental clearance for establishment of an All Weather Port (Minor) at Dholera, Gujarat in March, 2001.

(c) No, Sir.

(d) The project could be accorded clearance under the Coastal Regulation Zone Notification, 1991 only on 18.4.2006 as the complete information was received from the project authorities only on 27.2.2006.

(e) Does not arise.

Authority for testing sources of soft drinks

*427. SHRI T.T.V. DHINAKARAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of allegations of presence of pesticides in soft drinks;

(b) whether Government would constitute a separate authority to test samples of source of bottling of soft drinks; and

(c) the steps taken to ensure safety in this regard?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) to (c) The Centre for Science and Environment (CSE) has released a report on 2.8.2006 entitled "Analysis of Pesticide Residues in Soft Drinks".

The Ministry of Health and Family Welfare constituted an Expert Committee on 4.8.2006 to review the CSE Report including the methology adopted by CSE. The conclusion of the Expert Committee is that the report of CSE does not provide conclusive evidence for presence of different pesticides in the concentration reported. The